PTO/SB/08B

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid CMB control number Substitute for form 1449B/PTO Complete if Known 10/600.266 Application Number INFORMATION DISCLOSURE Filing Date June 20, 2003 STATEMENT BY APPLICANT First Named Inventor Fumitoshi Asai Art Unit 1614 (Use as many sheets as necessary) Examiner Name Brian S. Kwon Sheet of 3 Attorney Docket Number 13509 105003US

U.S. PATENT DOCUMENTS						
Examiner Initials *			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, When Relevant Passages or Relevan Fligures Appear	
		US 6,693,115	02-17-2004	Asai et al.		
	-		+		<u> </u>	

FOREIGN PATENT DOCUMENTS Examiner Cite Foreign Patent Document Publication Date Name of Patentee or Applicant of Cited Document Pages, Columns,						
xaminer Initials*	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	ľ
		Country Code - Number - Kind Code (If known)				
						Г
						Г
						r
						Г

Examiner Signature	Date Considered	

EXAMER Initial Inflamon, consistent, shelther or set darken as n continuous with MEP 800. Date in brough dataset for an continuous and not consistent in registent. Applications various datasets content to applicate. Applications various datasets content to particular and processing of the form with notice communication to applicate and processing of the form with notice and processing of the form of the processing of the processing of the form of the processing of the processing of the form of the processing of the processing of the form of the processing of the p

Substitute for form 1449B/PTO Complete if Known 10/600.266 Application Number INFORMATION DISCLOSURE June 20, 2003 Filing Date STATEMENT BY APPLICANT First Named Inventor Fumitoshi Asai Art Unit 1614 (Use as many sheets as necessary) Examiner Name Brian S. Kwon of 3 Sheet 2 Attorney Docket Number 13509.105003US

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		Asai, Fumitoshi et al., "Platelet inhibitory activity and pharmacokinetics of prasugrel (CS-747) a novel thienopyridine P2Y12 inhibitor: A single ascending dose study in healthy humans," Platelets, vol. 17, no. 4, pp. 209-217, June 2006	
		Chen et al., "Aspirin resistance is associated with a higher incidence of myonecrosis after nonurgent percutaneous coronary intervention despite clopidogrel pretreatment," J Am Coll Cardiol, 43:1122-6, 1125 (2004)	
		FDA Cardiovascular and Renal Drugs Advisory Committee, Silde Presentation and Transcript of Meeting, February 3, 2009, available at < http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials / Drugs/ CardiovascularandRenalDrugsAdvisoryCommittee/ ucm125999.htm>>	
		Goodman and Gilman, The Pharmacological Basis of Therapeutics, Fifth Edition, p. 25-26, 1975	
		Herbert, J.M. et al., "The anti-aggregating and antithrombotic activity of ticlopidine is potentiated by aspirin in the rat," Thromb. Haemost., vol. 76, pp. 94-98, 1996	
		Herbert, J.M. et al., "The anti-aggregating and antithrombotic activity of clopidogrel is potentiated by aspirin in several experimental models in the rabbit," Thromb. Haemost., vol. 80, pp. 512-518, 1998	
		lkeda, "Preface: Antiplatelet Therapy- An Update," Haemostasis, vol. 30, Suppl. 3, 2000, p. 1	
		Jakubowski, J.A. et al., "A multiple dose study of prasugrel (CS-747), a novel thienopyridine P2Y12 inhibitor, compared with clopidogrel in healthy humans," British Journal of Clinical Pharmacology, vol. 63, no. 4, pp. 421-430, October 31, 2006	
		Jarvis et al., "Clopidogrel: A Review of its Use in the Prevention of Atherothrombosis," Drugs, 60(2):347-377, August 2000, Abstract	
		Jemberg, Tomas et al., "Prasugrel achieves greater inhibition of platelet aggregation and a lower rate of non-responders compared with topidogrel in aspirin-treated patients with stable coronary artery disease," European Heart Journal, vol. 27, pp. 1166-1173, 2006	

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid CMB control number Substitute for form 1449B/PTO Complete if Known 10/600.266 Application Number INFORMATION DISCLOSURE Filing Date June 20, 2003 STATEMENT BY APPLICANT First Named Inventor Fumitoshi Asai

Art Unit (Use as many sheets as necessary) Examiner Name

1614 Brian S. Kwon Sheet 3 of 3 Attorney Docket Number 13509.105003US

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		Lev et al., "Aspirin and Clopidogrel Drug Response in Patients Undergoing Percutaneous Coronary Intervention," Journal of the American College of Cardiology, 47(1):27-33 (2006)	
		Matsushima, Nobuko et al., "Platelet inhibitory activity and pharmacokinetics of prasugrel (CS-747) a novel thienopyridine P2Y12 inhibitor: A multiple-dose study in healthy humans," Platelets, vol. 17, no. 4, pp. 218-226, June 2006	
		PLAVIX® Prescribing Information, "Dosage and Administration," revised May 2009	
		Sacco et al., "Update on Antiplatelet Therapy for Stroke Prevention," Arch. Intern. Med., 160, June 12, 2000, 1579-1582, Abstract	
		Steinhubl, "Antiplatelet Agents in Cardiology: The Choice of Therapy," Ann. Thorac. Surg, 70:S3-8, 2000, presented Jan. 22-23, 1999	
		TICLID® Prescribing Information, revised March 2001	
		Van de Graaff, "Antiplatelet medications and their indications in preventing and treating coronary thrombosis," Annals of Medicine, 32(8), November 2000, p. 561-571, Abstract	
		Van de Graaff et al., "Variable Interindividual Responses to Antiplatelet Therapies- Do They Exist, Can We Measure Them, and Are They Clinically Relevant?" Heart Drug, 1(1):35-43 (2001), available online August 2000	
		Weerakkody, Govinda J. et al., "Comparison of Speed of Onset of Platelet Inhibition After Loading Doses of Clopidogrel Versus Prasugrel in Healthy Volunteers and Correlation With Responder Status," Am J Cardiol, vol. 100, pp. 331-336, 2007	

Examiner Signature	Date Considered	

COMMINION that of all contracts whether or not date, an extension with MPP 000 Date to broady other full as extensions and not contract. The property of the time when the commission is required, adoption of the property of the time when the property of the contract of the property of the property of the contract of the property of t